



Date: August 14, 2018  
To: Contra Costa Board of Supervisors  
From: Daniel Peddycord, Public Health Director  
Marilyn Underwood PhD, Environmental Health Director  
Subject: Update on Safe Drug Disposal Program

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**Background:**

On December 13, 2016, the Contra Costa Board of Supervisors introduced Ordinance No. 2016-24 ("Ordinance"), the Safe Drug Disposal Ordinance. Final adoption occurred on December 20, 2016. The Ordinance requires drug manufacturers to establish and pay for a system to collect and dispose of unwanted pharmaceutical drugs. The goal is to establish at least three drop-off sites in each of the five supervisorial districts in locations that allow for convenient and equitable access by residents of the unincorporated areas of those districts. Preference is given for establishing drop-off sites in pharmacies and law enforcement agencies, which can accept controlled drugs, such as opioid based pain medications. The Board directed that a follow up report be provided.

On September 26<sup>th</sup>, 2017, a follow up report was provided, at the request of the Board, to address the following:

- An update on implementation of the Ordinance
- Advice on whether to establish additional requirements on the drug stewardship organization, specifically in terms of how it is organized as an entity.
- Opportunities to include hospitals as drop-off sites versus limiting drop-off sites to retail pharmacies and law enforcement.
- Advisability of including sharps as part of the drug takes back program.
- Progress to seek adoption of similar ordinances in each city within the County.
- Update on a Public Awareness Campaign to increase awareness of the program and provide useful information to pharmacies, law enforcement, cities and citizens, hazardous material collectors, and sanitation districts.
- Ordinance amendments for consideration.

To emphasize the importance of a continued focus on the national opioid epidemic, a March 8, 2018, report by the Centers for Disease Prevention (CDC) reported that from 2015 to 2016 opioid overdose deaths increased 27.7%, indicating a worsening of the opioid epidemic. Further, during the period from July 2016-September 2017, emergency department (ED) visits for opioid overdose, among those age 11 and older, increased 29.7% overall. . . <https://www.cdc.gov/vitalsigns/>

### **Progress to Date on Implementing the Ordinance:**

As reported in September of 2017, following final adoption of the Ordinance, the Public and Environmental Health Divisions of Contra Costa Health Services (EH) endeavored to contact pharmaceutical wholesalers to alert them to the new Ordinance, to request information confirming that they sell prescription and/or over-the-counter drugs in Contra Costa County, and to provide the names and manufacturers of all covered drugs that the drug wholesaler sells or distributes in the unincorporated area of the county. Letters were sent to over 3,000 purported drug wholesalers.

As of May 1, 2017, 95 wholesalers responded indicating that they are exempt from the Ordinance and 60 responded confirming that they wholesale drugs in Contra Costa County. Some 1,632 drug producers were subsequently contacted by letter in early June of 2017 about their potential responsibility to participate in the County's safe drug take-back ordinance. This letter referred to the Ordinance and relevant time lines and advised them of the deadline to provide a notice of intent to participate in the Pharmaceutical Product Stewardship Work Group (PPSWG) program<sup>1</sup> or a different stewardship program.

On June 30, 2017, the Division of Environmental Health received an email from MED-Project, a pharmaceutical product stewardship consortium, informing us that they would be submitting a plan to comply with the County Ordinance on behalf of 378 producers of covered drugs. That number has since grown to nearly 450. Many of the producers that were submitted by MED-Project are on the list to whom letters were sent. Environmental Health has also been in contact with the Plan Director for MED-Project, based in Washington, D.C.

As of September 7, 2017, Environmental Health received responses from 81 producers indicating that they would be participating by working with MED-Project. One producer indicated they would be submitting a plan, not participating with MED-Project. Another 72 responded in the following manner: 48 indicated they do not sell drugs that are used in the home; 30 responded that they do not sell in Contra Costa County, and 31 chose the "Other" category and provided a text response. The text responses most often stated that they were a distributor and not a producer or that they produced medical products and they do not produce pharmaceuticals.

Consistent with the time line required, producers submitted their plans to comply with the County Ordinance in January of 2018. MED-Project submitted a comprehensive plan. Two other smaller producers, Medac and CAO Group, Inc., submitted plans as well. On behalf of the County Health Officer, the plans were reviewed

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<sup>1</sup> A mechanism by which to contact and work with the wholesalers and drug manufacturers is via the PPSWG and MED-Project. PPSWG is a membership association for drug manufacturers and marketers. The group was formed to address the complexities and uncertainties of new laws that govern the disposal of unused and unwanted pharmaceutical products. PPSWG provides "members with a platform to organize and present science-based data about safe pharmaceutical disposal practices. PPSWG also coordinates the industry's efforts to raise awareness about appropriate disposal methods, and to respond to disposal laws." MED-Project is the name for the PPSWG's activity on the drug take-back front. There is a website that they have developed to disseminate information about drug disposal, and they add information about each of the jurisdiction's that have programs as implementation unfolds: <http://www.med-project.org/locations>

by staff of the Environmental and Public Health Divisions of Contra Costa Health Services and some revisions and clarification were requested.

On June 25<sup>th</sup>, 2018 Contra Costa Health Services approved the revised plan submitted by Med-Project, that is attached for reference. Under the Ordinance, Med-Project has 90 days from plan approval to commence operation of the stewardship program described in the plan. This will include establishment of the drop-off sites and mail-back services described in the plan. Based on this requirement, Staff anticipates a functioning program by the fall of 2018. Med-Project has expressed interest in a kick-off event and we are coordinating efforts to that end.

One aspect that is key to the MED-Project plan is their intention to install disposal kiosk at any participating pharmacy or law enforcement agency that meets legal requirements. This implies that we should expect to see more than the minimum of 15 drop off sites (disposal kiosk) required in the County Ordinance.

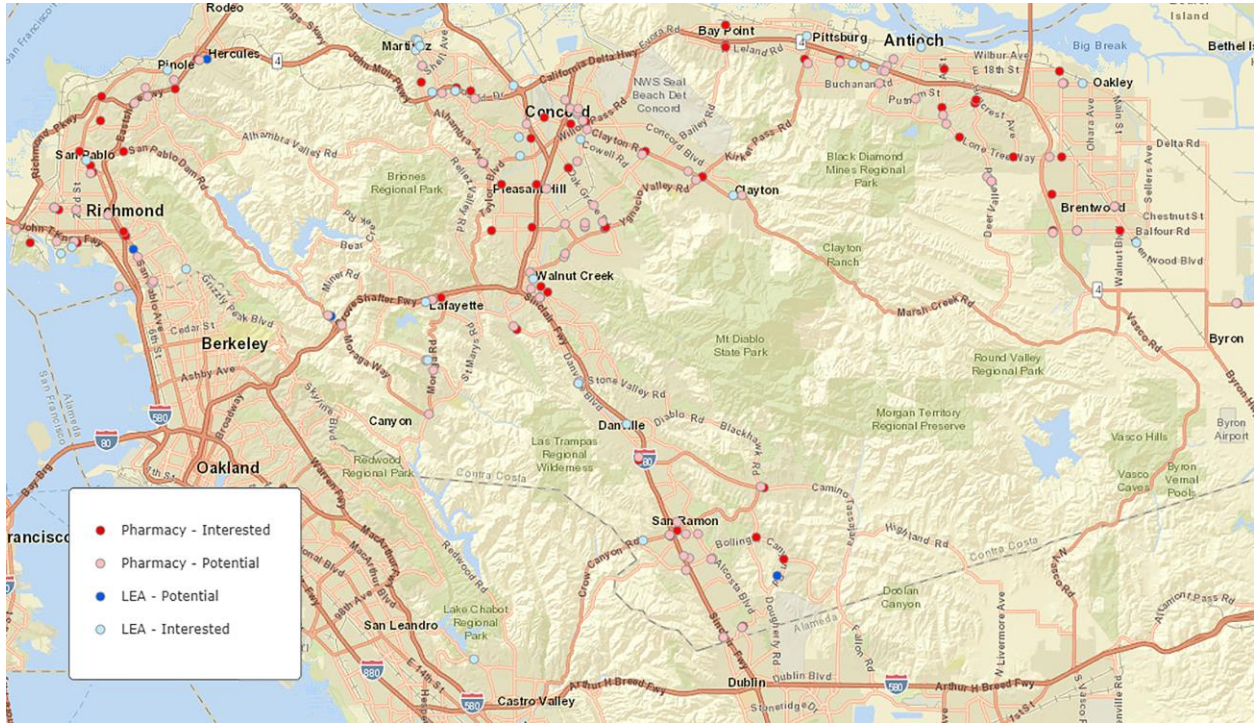
**Highlight of Details in MED-Project - Safe Drug Disposal Plan:**

The following is a summary of the key components of the Med-Project stewardship plan approved by the health officer:

**1. Kiosk Drop-Off Site Locations**

MED-Project notified 163 pharmacies and 33 law enforcement agencies located in the county of the opportunity to serve as a Kiosk Drop-Off Site Host. Of those, 94 pharmacies and 29 law enforcement agencies expressed interest in participating in the stewardship program.

A map of the interested and potential Kiosk Drop-Off Site Host locations is noted below.



As of July 2018, specific locations for drop-off sites (disposal kiosk) are still under negotiation between Med-Project and interested Pharmacies and Law Enforcement Agencies (collectors). **As noted above, MED-Project intends to include in its program all retail pharmacies and law enforcement agencies (collectors) that are willing to serve voluntarily as a Drop-Off Site for unwanted pharmaceuticals and can satisfy all applicable legal requirements. This will effectively create a county-wide program, over time.** Pharmacies and law enforcement agencies that host drop-off sites now may participate in the program by signing agreements with MED-Project and, if necessary, modifying their Drug Enforcement Agency (DEA) registrations. MED-Project plans to work with these Kiosk Drop-Off Site Hosts to transition to MED-Project's program and its waste vendor, Stericycle Specialty Waste Solutions, Inc..

The construction and location of the kiosks are regulated by the DEA under Title 21, Part 1317 of the Code of Federal Regulations (C.F.R.) ("DEA Regulations"), and the California Board of Pharmacy under its prescription drug take-back services regulations. (Cal. Code Regs., tit. 16, § 1776 et seq.) The MED-Project kiosks will be made of heavy gauge steel and have multiple locks, tamper-proof slots and commercial hinges, and be accessible to wheelchair users. The plan indicates that kiosks at hospitals or clinics with an on-site pharmacy will be placed in an area regularly monitored by employees but not near areas of the facility where emergency or urgent care is provided. (21 C.F.R. § 1317.75, subd. (d)(2)(i).)

## 2. Kiosk Collection – DEA Regulations

Under the DEA Regulations, pharmacy Kiosk Drop-Off Sites must dispose of sealed inner liners and their contents either on-site, through common or contract carrier delivery to or pick-up by a distributor or reverse

distributor, or with DEA assistance. (21 C.F.R. § 1317.05(c)(2)(iv).) Section 1317.75(c) prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk. Additionally, Section 1317.60 limits inner liner access to employees of the collector and requires two employees to immediately seal the inner liner upon its removal from the pharmacy kiosk's permanent outer container. (21 C.F.R. § 1317.60(b)-(c).) Section 1317.75(g) provides that pharmacy kiosk inner liner installation or removal shall be performed "by or under the supervision of at least two employees of the authorized collector." The pharmacy kiosk sealed inner liner must not be opened, x-rayed, analyzed, or otherwise penetrated. (21 C.F.R. § 1317.60(c).)

At law enforcement Kiosk Drop-Off Sites, the service vendor, Stericycle Specialty Waste Solutions, Inc. and the law enforcement agency will maintain any records of removal, storage, or destruction of the collected unwanted pharmaceuticals in a manner consistent with the law enforcement agency's recordkeeping requirements for illicit controlled substances evidence pursuant to Section 1317.35. Law enforcement will record the unique barcode number and size of the sealed inner liner transferred to Vendor. See (21 C.F.R. § 1317.35.) Additionally, unwanted pharmaceuticals will be stored in a manner to prevent the diversion of controlled substances and consistent with the law enforcement agency's standard procedures for storing illicit controlled substances

### **3. Frequency of Pick-Up**

Initially, all Kiosk Drop-Off Site Hosts not previously hosting a kiosk will be scheduled for a monthly pick-up from the kiosk. MED-Project will communicate with the Kiosk Drop-Off Site Host in the event the frequency of pick-up needs to be changed based on the volumes collected over time. The service vendor, Stericycle Specialty Waste Solutions, Inc., will monitor volumes collected per service to ensure that all sites are receiving the appropriate service frequency. The vendor will manage pick-up services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating Kiosk Drop-Off Site and monitor the weight of collected unwanted pharmaceuticals at each participating Kiosk Drop-Off Site.

### **4. Procedures if a Kiosk is Full Prior to Scheduled Pick-Up**

The Kiosk Drop-Off Site Host shall be instructed to lock the drop-slot to the kiosk when the kiosk is full and notify MED-Project of the need for service if prior to the scheduled service date. Service will be done within 2 to 3 business days.

### **5. Implementation:**

MED-Project anticipates that establishment of Kiosk Drop-Off Sites within 90 days of approval of the Plan. Once all drop-off locations are fully operational, the program expects to collect approximately 360 pounds per Kiosk Drop-Off Site during each calendar year, based on collection totals in other jurisdictions. Assuming 15 Kiosk Drop-Off Sites are operational for a full year, MED-Project anticipates collecting approximately 5,400 pounds of unwanted pharmaceuticals from Kiosk Drop-Off Sites in 2019.

Should Take-Back events be necessary MED-Project anticipates collection of 50 to 200 pounds of unwanted pharmaceuticals per event, based on collection totals in other jurisdictions.

MED-Project mail-back packages have a capacity of 8oz. per package

### **6. Patient Privacy**

Instructions at each Kiosk Drop-Off Site Host location will inform people who deposit unwanted pharmaceuticals that they should completely cross out, remove, or otherwise make unreadable all personally

identifiable information on the drug containers and packaging before depositing them in the kiosk. In cases where people follow the instructions, there will be no personally identifiable information.

In addition to kiosk signage, MED-Project promotional and educational materials will encourage residents to protect their information by ensuring that identifiable information is not present before depositing containers into kiosks.

### **City Participation:**

The Ordinance is not enforceable within cities. However, the County health officer acts as the city health officer in all of the cities in Contra Costa County. If cities adopt substantially similar ordinances, the County health officer could then coordinate the take-back programs in both the cities and the unincorporated area. To the extent a city ordinance established different standards with regard to location or number of take-back sites to serve incorporated areas, a drug stewardship plan already approved by the County health officer – such as the MED-Project plan -- could simply be amended to conform to the new standards. The Ordinance does not require amendment to allow cities to adopt their own ordinances. However, staff has evaluated possible amendments to the Ordinance that would, among other things, clarify the above process.

In the course of evaluating possible amendments to the Ordinance, staff became aware of activity in the California legislature pertaining to pharmaceutical waste. As written when introduced in February 2017, Senate Bill 212 would only have added a definition of “home-generated pharmaceutical waste” to the Medical Waste Management Act. But in June 2018, the bill was substantially amended. If passed as currently drafted, the legislation would instead add a new chapter to the Public Resources Code to establish a statewide pharmaceutical and sharps waste stewardship program, under which a drug manufacturer would be required, either individually or through a stewardship organization, to establish, implement and pay the costs of a stewardship program. CalRecycle would be the enforcing agency, and would be empowered to impose civil penalties on manufacturers for selling pharmaceuticals that are not subject to a stewardship plan.

One provision of the legislation would “preempt a local stewardship program for covered products enacted by an ordinance that has an effective date on or after April 18, 2018.” This language would not affect the enforceability of the Ordinance, which took effect in January 2017. Amending the Ordinance, however, could give rise to preemption arguments, if this provision ultimately becomes law. Under the circumstances, staff determined that evaluation of potential risks presented by amending the Ordinance is warranted prior to bringing amendments forward.

### **Public Awareness and Notifying Key Stakeholders:**

The Ordinance requires the producers of covered drugs to provide annual written notices to nonparticipating and new retail pharmacies located in the county regarding the opportunity to participate as collectors. Hence, the map noted above may change year by year if nonparticipating and new pharmacies decide to participate in the program. In addition the producers are required to implement measures that are designed to result in the use of the collection services by county residents. MED-Project has proposed to outreach to not only the general public but also pharmacies, health care providers, veterinary providers, public health agencies, and law enforcement agencies. Med-Project has also indicated that they will provide educational and mailing materials as well as media outreach in English, Spanish, Chinese and Vietnamese.

In addition Contra Costa Health Services will continue to maintain a web page with information for the public regarding the safe disposal of unwanted medications: <http://cchealth.org/safe-drug-disposal/>

The California Product Stewardship Council also maintains a web page of resources regarding the safe disposal of unwanted medications. The website is informative and includes packing instructions and a bin finder. <https://dontrushtoflush.org/>

### **Other related activity:**

**California Counties:** On July 3<sup>rd</sup>, 2018 Tehama County adopted an Extended Producer Ordinance for medications and sharps joining 10 other counties that have adopted EPR ordinances covering medications. (San Francisco, San Mateo, Santa Barbara, Santa Clara, Contra Costa, Marin, Sonoma, San Luis Obispo and Los Angeles)

**DEA:** The U.S Drug Enforcement Administration (DEA) continues to sponsor their periodic drug take-back events. Their next event, the 15<sup>th</sup> since the inception of the program, was held on Saturday April 28<sup>th</sup>, 2018 at several locations across the County. The most recent prior DEA Prescription Take-Back event was held Saturday, October 28, 2017.

**Washington State:** In February 2018, the Washington House and Senate approved new secure medicine return legislation and on March 29<sup>th</sup>, Governor Islee signed the bill into law. The law (ESHB 1047) requires drug manufacturers to finance and coordinate a convenient and secure take-back system for unused medicines. When the program is launched, residents will be able to bring leftover prescription and over-the-counter drugs into their local pharmacies, hospitals and other places for safe disposal. In areas without collection sites, prepaid return mailers will be provided. If this bill passes into law, it will be the first comprehensive drug take-back program in the nation that is provided by the pharmaceutical industry. Similar local laws are already in place in King, Snohomish, Kitsap, Pierce, Clallam, and Whatcom Counties requiring pharmaceutical manufacturers to provide a drug take-back program. The statewide law will expand access to the program to all residents of Washington. To find out more about the Secure Drug Take-back Act: <http://app.leg.wa.gov/bills/summary?BillNumber=1047&Year=2018>

**New York:** On July 10, 2018, New York Governor Andrew Cuomo signed a Drug Take Back Act creating a statewide disposal program for covered drugs. Previously on, February 20, 2018 The New York State Department of Environmental Conservation (NYS DEC) [announced](#) that 172 new retail pharmacies, hospitals, and long-term care facilities have enrolled in its statewide pilot drug take-back program, bringing the total to 246. The two-year pilot is funded by \$2 million from the state's Environmental Protection Fund.

**Walmart:** On Wed, 17 Jan 2018 Walmart announced that they will begin offering a free DisposeRx home disposal pouch when dispensing opioid prescriptions. However, this may be limited to certain markets, may require pre-approval from State and local solid waste and hazardous materials authorities and may discourage consumers from using Kiosk to dispose of other, non-opioid medication. <https://www.forbes.com/sites/elliekincaid/2018/01/17/walmart-to-give-away-kits-to-dispose-of-opioids-at-home/#4088fbae139f>

Their website claims: DisposeRx drug destroying gel uses proprietary, patent-pending technology made of solidifying cross-linking chemical polymers that permanently sequester all medications. The Counties of Alameda, Contra Costa, Marin, San Francisco, San Mateo, Santa Barbara, and Santa Clara are asking Walmart to refrain from deploying the chemical deactivation process, strictly for opioids, and rather to consider:

(1) hosting MED-Project medicine collection kiosks in Walmart and Sam's Club stores located in our counties; and (2) refraining from providing the medication disposal packets at these same locations. .

**CVS Pharmacy:** CVS Pharmacy is actively working to roll out kiosk placement and are initiating a pilot project in Santa Cruz.

**Walgreens:** As previously reported Walgreens has taken the lead as the nation's first large retail pharmacy chain to establish a drug take-back program. To date, Walgreens has elected not to become part of the MED-Project program, but remains committed to improving options for the safe disposal of medications. From the program's inception in February 2016 to April 2017, the retailer installed disposal kiosks in more than 600 of their pharmacies located in 45 states. By October of 2017 the retailer reported collecting 155 tons of unwanted medication and has established a two year goal to collect an additional 300 tons. Walgreens has also more recently announced an expansion of the kiosk program to 1500 kiosks nationwide. <http://news.walgreens.com/press-releases/general-news/amerisourcebergen-blue-cross-blue-shield-association-pfizer-and-prime-therapeutics-join-walgreens-to-combat-prescription-drug-abuse-by-expanding-safe-medication-disposal-program.htm>